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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/977,827	10/15/2001	Johannes Maria Franciscus Gerardus Aerts	294-32 DIVII/CON	4648

7590

06/16/2004

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EXAMINER

PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/977,827

Applicant(s)

AERTS, JOHANNES MARIA
FRANCISCUS GERARD

Examiner

Rebecca E. Prouty

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 1 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 15-29 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14, 30 and 32-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 1-31 and newly presented claims 32-36 are still at issue and are present for examination.

Claims 15-29 and 31 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the response filed 8/8/03

Applicants' arguments filed on 4/1/04, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

The terminal disclaimer filed on 4/1/04 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of 5,928,928 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim 4 is objected to because of the following informalities: "having" in line 4 should be "has". Appropriate correction is required.

Claims 1-14, 30, and 32-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to

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particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 (upon which Claims 2-14, 30, and 32-36 depend) is confusing in the recitation of "a human chitinase having an amino acid sequence selected from the group consisting of an amino acid sequence depicted in SEQ ID NO:4, or an essentially corresponding form of said chitinase having a sequence homology of at least 70%, having chitin-hydrolyzing activity" as it is unclear what Markush group is being recited as a Markush group recitation should include the word "and" prior to the last member of the group but "and" does not occur in the claim at all, it is unclear if any "an essentially corresponding form of said chitinase having a sequence homology of at least 70%, having chitin-hydrolyzing activity" must be a "human chitinase" (i.e., a naturally occurring protein) and the claim lacks the word "and" prior to "having chitin-hydrolyzing activity". For purposes of examination this claim is assumed to recite "A substantially isolated or purified chitinase, said chitinase having an amino acid sequence selected from the group consisting of SEQ ID NO:4 and sequences having at least 70% identity to SEQ ID NO:4".

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Claims 2, 3 and 32 are indefinite in the recitation of "essentially corresponding to" as it is unclear how many changes can be made within the recited sequence and still be included within this phrase. While page 12 of the specification teaches that generally the changes will be less than 30% of the total number of nucleotides in the recited sequences, there is nothing which indicates that this term is limited thereto. For purposes of examination this phrase is interpreted to mean at least 70% identity to. While applicants have amended claims 1 and 4 to clarify the meaning of the phrase within these claims, no such amendments have been made to the instant claims.

Claims 1-3, 5-14, 30, and 33-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling the human chitinases of SEQ ID NOS: 4 or 6 or chitinases encoded by nucleic acids which will hybridize to the nucleic acids of SEQ ID NOS: 3 or 5 under specific highly stringent conditions, does not reasonably provide enablement for any chitinase having 70% identity to SEQ ID NOS:4 or 6. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. The rejection is explained in the previous Office Action.

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Applicants appear to believe that the limitation of the claims to chitinase having 70% identity to SEQ ID NOS:4 or 6 overcomes the instant rejection, however for the all the reasons previously presented the current claims remain substantially broader than the enabling disclosure. As such this rejection is maintained.

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is explained in the previous Office Action.

Applicants argue that the specification states that long term cultured macrophages secrete chitinolytic enzymes and an enzyme active against dye labeled β -glucan. However, the specification does not disclose any information about this supposed β -glucan sufficient for the skilled artisan to distinguish it from other compounds, obtain it and use it, i.e. what are its characteristic identifying features? As such the specification fails to sufficiently describe and enable the claimed composition.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca Prouty, Ph.D. whose telephone number is (571) 272-0937. The examiner can normally be reached on Monday-Friday from 8:30 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to read "Rebecca Prouty", with a stylized flourish at the end.

Rebecca Prouty
Primary Examiner
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